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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,057	10/05/2000	Edwin W. Ades	14114.0381U2.	7894
23859	7590	10/18/2005	EXAMINER	
NEEDLE & ROSENBERG, P.C.			SWARTZ, RODNEY P	
SUITE 1000			ART UNIT	
999 PEACHTREE STREET			PAPER NUMBER	
ATLANTA, GA 30309-3915			1645	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/600,057

Applicant(s)

ADES ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 August 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): see attached Detailed Action.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: 20-27.
Claim(s) objected to: _____.
Claim(s) rejected: 13, 14, 16-19.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Final Office Action, received 22 August 2005, is acknowledged. Claims 16, 20, 25, and 27 have been amended. Claims 15, 28, and 29 have been canceled.
2. Claims 13-14 and 16-27 are pending and under consideration.

Rejections Moot/Withdrawn

3. The rejection of claims 28 and 29 under 35 U.S.C. 112, second paragraph, as being indefinite for "a high five cell", is moot in light of the cancelation of the claims.
4. The rejection of claim 15 under 35 U.S.C. 112, second paragraph, as being indefinite for "substantially free", is moot in light of the cancelation of the claim.
5. The rejection of claims 20-24 under 35 U.S.C. 112, first paragraph, scope of enablement for vaccination with any/all preparations of lipidated PsaA, is withdrawn in light of applicants' amendment of claims to recite that the lipidated PsaA is recombinantly produced in a High Five cell
6. The rejection of claim 27 under 35 U.S.C. 112, second paragraph, as being indefinite for "a high five cell", is withdrawn in light of the amendment of the claim and applicants' explanation.
7. The rejection of claims 25-27 under 35 U.S.C. 112, second paragraph, as being indefinite for "immunogenic fragment", is withdrawn in light of the amendment of the claim and applicants' explanation.

Rejections Maintained

8. The rejection of claims 13, 14, and 16-19 under 35 U.S.C. 112, second paragraph, as being indefinite for "substantially free", is maintained for reasons of record.

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Applicants argue that the meaning of "substantially free" is the meaning that is understood and accepted as definite in the patent law, as evidenced by numerous patents that use this term in their claims.

The examiner has considered applicants' argument, but does not find it persuasive. To understand the presence of the term "substantially free" in prior patents, the entire prosecution history of each patent must be assessed to determine if the metes and bounds of the term were adequately provided to define the term and allow its use in the claims. In the instant application, the metes and bounds of the term have not been adequately defined. For example, does "substantially free from lipopolysaccharides and contaminant proteins" mean that the claimed PsaA is 10% pure or 90% pure. Thus, what level of contaminating proteins and lipopolysaccharides is encompassed by the instant claims?

Conclusion

9. Claims 13, 14, and 16-19 remain finally rejected. Claims 20-27 appear to be free of the prior art of record.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

October 17, 2005